

10/526290

BT01 Rec'd PCT/PTT 0 1 MAR 2005

1 "Blood Regulation Device"

2

3 The present invention relates to stents for
4 connecting a first compartment to a second
5 compartment. In particular, the invention relates
6 to cardiovascular stents e.g. for connection of the
7 left ventricle of the heart to a coronary artery.

8

9 Coronary artery disease is a major problem throughout
10 the world, particularly in Western society.

11 Coronary arteries, as well as other blood vessels,
12 can become clogged with plaque, impairing the
13 efficiency of the heart's pumping action. This can
14 lead to heart attacks, angina and death.

15

16 A number of methods are used to treat clogged
17 coronary arteries such as bypass operations or
18 balloon angioplasty.

19

20 In bypass operations one or more venous segments are
21 inserted between the aorta and the coronary arteries
22 to bypass the blocked portion of the coronary artery
23 such that an unobstructed flow of blood and thus

CONFIRMATION COPY

1 blood supply to the heart is achieved. More than
2 500,000 bypass procedures are performed in the US
3 every year.
4
5 However, bypass surgery is a very intrusive
6 procedure requiring expensive and time-consuming
7 surgery. During a bypass operation, an incision is
8 made through the patient's skin and the patient is
9 placed on a bypass pump such that the heart can be
10 operated on, while it is not beating. A saphenous
11 vein graft is harvested from a patient's leg and the
12 vein is then grafted into position between the aorta
13 and the coronary artery to allow unobstructed blood
14 flow. This surgery is both traumatic to the patient
15 and requires a substantial period of time in
16 hospital and prolonged convalescence.
17
18 In some circumstances a balloon angioplasty
19 procedure is used instead of the above method, to
20 treat coronary artery plaque occlusion. In this
21 case a deflated balloon catheter is placed within
22 the narrowed segment of the coronary artery. The
23 balloon is then inflated to a high pressure,
24 transmitting circumferential pressure to the plaque
25 occluding the artery, compressing the plaque and
26 thus increasing the diameter through which blood can
27 flow.
28
29 Although balloon angioplasty is minimally invasive,
30 this procedure can only be used in a limited number
31 of circumstances.
32

1 In addition to the two techniques discussed above,
2 which have been traditionally used to treat coronary
3 artery occlusion, a more recent procedure allows a
4 stent to be positioned between the coronary artery
5 and the left ventricle of the heart such that blood
6 can flow unobstructed from the left ventricle of the
7 heart to the coronary artery, bypassing the occluded
8 portion of the coronary artery. The stent may be
9 positioned between the left ventricle of the heart
10 and the coronary artery using a less invasive
11 procedure than that required for coronary bypass
12 surgery.

13
14 Typically the stent is a conduit with a passage
15 extending longitudinally therethrough. Generally a
16 stent is cylindrical in cross section and is
17 generally an elongate tube.

18
19 A disadvantage of providing a stent extending from
20 the left ventricle of the heart to the coronary
21 artery is that during diastole blood may reflux from
22 the coronary artery back into the left ventricle of
23 the heart. Such refluxes of blood are undesirable.

24
25 Some reports have indicated that backflow of
26 oxygenated blood back into the left ventricle
27 chamber of the heart during diastole can cause the
28 the myocardium to receive an inadequate supply of
29 blood. This can lead to the myocardium becoming
30 ischemic. Indeed, some studies have suggested that
31 measurement of the blood flow during systole and the
32 backflow during diastole indicates that only a 30

1 percent net flow rate of blood from the left
2 ventricle chamber into the artery is achieved
3 following introduction of a stent between the two
4 compartments.

5
6 There remains a need for improved (more efficient)
7 stents.

8
9 The present inventor has overcome a number of
10 problems of stents of the prior art.

11
12 According to a first aspect of the present invention
13 there is provided a cardiovascular stent comprising
14 a generally tubular body and a synthetic one-way
15 valve capable of moving from a first open position
16 to a second closed position, wherein, in use,
17 movement of fluid, e.g. blood, in a first direction
18 through the stent causes the valve to adopt the open
19 position and movement of fluid in a second opposite
20 direction causes the valve to adopt the closed
21 position.

22
23 The valve is deemed to be in the closed position
24 when it restricts the passage of fluid in the second
25 direction e.g. from a second compartment to a first
26 compartment. A stent as described by the present
27 invention can be used to enable the movement of
28 fluid from a proximal position in a first
29 cardiovascular compartment to a distal position in
30 the same cardiovascular compartment or a different
31 cardiovascular compartment.

32

1 Preferably in the closed position, the valve allows
2 movement of fluid in the second direction of less
3 than 40% that when the valve is in the open
4 position.

5
6 More preferably in the closed position the valve
7 allows movement of fluid in a second direction of
8 less than 30%, preferably less than 20%, even more
9 preferably less than 10%, even more preferably less
10 than 5%, even more preferably less than 2% and most
11 preferably less than 1% that when the valve is in
12 the open position.

13
14 A stent with a synthetic valve is advantageous as it
15 can restrict the passage of fluid in a second
16 direction, e.g. from a second compartment to a first
17 compartment, e.g. from a coronary artery to the left
18 ventricle of the heart. This provides for an
19 increase in the net flow rate of blood from the
20 first compartment into the second compartment and
21 minimises the likelihood of e.g. the myocardium, of
22 which the coronary artery provides the blood supply,
23 receiving an inadequate supply of blood.

24
25 In such an embodiment the movement of fluid in the
26 first direction e.g. from the first compartment to
27 the second compartment causes a pressure difference
28 across the valve sufficient to cause the valve to
29 adopt the open position. Fluid flow in the second
30 opposite direction, e.g. from the second compartment
31 to the first compartment across the valve, causes
32 the valve to adopt the closed position.

1
2 Further, the use of a synthetic valve has the
3 further advantage that a vein does not need to be
4 harvested from the patient.

5
6 Preferably in the absence of movement of fluid in
7 either a first or second direction the valve adopts
8 the closed position. Thus preferably the valve is
9 resiliently biased towards the closed configuration.

10
11 Preferably the stent is for use in linking
12 cardiovascular compartments.

13
14 Preferably the first compartment is a first
15 cardiovascular compartment and the second
16 compartment is a second cardiovascular compartment.

17
18 A cardiovascular stent is a stent suitable for use
19 to link one part of a cardiovascular compartment to
20 another part of the same cardiovascular compartment
21 or to another cardiovascular compartment.

22
23 A cardiovascular compartment is defined as any organ
24 or any structure of the circulatory system including
25 an artery, vein or chamber of the heart.

26
27 In a preferred embodiment the stent is for use as a
28 stent between the left ventricle of the heart and a
29 coronary artery.

30
31 Preferably the valve is formed from resilient
32 material.

1

2 A valve formed from resilient material is
3 advantageous as it requires few mechanical
4 components to enable the valve to move between the
5 open and closed positions and thus there is less
6 likelihood of damage to red blood corpuscles moved
7 through the stent.

8

9 Preferably the flexible resilient material is a
10 suitable biostable biocompatible polymer.

11

12 Preferably the flexible resilient material includes
13 Elast-Eon™, Biomer or Biospan.

14

15 Details of the polymer Elast-Eon™ can be found in
16 WO98/13405, WO92/00338, WO92/09467, WO99/01496.

17

18 In an embodiment in which the valve is formed from
19 resilient material, in the closed position,
20 preferably at least a portion of the aperture formed
21 by the resilient material of the valve is
22 ellipsoidal shape in cross-section. This
23 ellipsoidal shape restricts blood flow from the
24 second cardiovascular compartment into the first
25 cardiovascular compartment.

26

27 Preferably the valve is constructed such that
28 movement of fluid such as blood in the first
29 direction through the stent urges the resilient
30 material of the valve to adopt a configuration in
31 which the aperture defined by the material is
32 substantially circular in cross-section thereby

1 enabling increased fluid to flow through the valve
2 and thus through the stent. Hence, with the
3 circular aperture increased flow from the first
4 cardiovascular compartment into the second
5 cardiovascular compartment is provided.

6
7 In an alternative embodiment the valve may comprise
8 at least two leaflets formed from resilient material
9 which when fluid is flowing in the second direction
10 through the stent or when no fluid is flowing
11 through the stent, the leaflets are urged towards
12 each other such that the passage of fluid e.g. blood
13 is minimised. In this embodiment, movement of fluid
14 in the first direction e.g. from a first compartment
15 to a second compartment urges the leaflets of the
16 valve to move apart from each other enabling the
17 passage of fluid through the stent.

18
19 The valve may be located at any position in the
20 stent.

21
22 Preferably the valve is located at either end of the
23 stent.

24
25 Such an embodiment is advantageous as a valve
26 portion of the stent can extend into a
27 cardiovascular compartment. This can be of
28 importance, for example, if the stent is for use
29 between the left ventricle of the heart and the
30 coronary artery as positioning of the valve in the
31 heart muscle may restrict the movement of the valve,
32 as the muscle contracts and relaxes.

1
2 Preferably the valve is integral to the stent.

3
4 Although a stent may be located and then valve means
5 provided on the stent, it is preferable if the stent
6 and valve are provided in one unit such that they
7 can be located between the cardiovascular
8 compartments in a single procedure.

9
10 The stent may be constructed of any suitable
11 material.

12
13 The stent may comprise a suitable rigid
14 biocompatible metal which may include, but is not
15 limited to one or more of stainless steel, spring
16 steel, Nitinol and / or a flexible resilient
17 material.

18
19 Preferably the stent may be constructed from
20 scaffold mesh.

21
22 Preferably the stent comprises a flange portion
23 located towards or at one end of the stent.

24
25 This is advantageous as when the stent is pushed
26 into tissue to provide a passage between two
27 compartments the depth of the stent in the tissue
28 can be controlled by the flange portion. If, for
29 example, the flange portion is towards or at the
30 rear portion of the stent, the front portion being
31 the portion inserted first into the tissue, on
32 pushing the stent into tissue from one compartment

1 to another the flange provided at the rear will
2 prevent the stent being pushed too far into the
3 tissue, ensuring that the lumen of the stent extends
4 from a first compartment into a second compartment.
5 Moreover the flange portion can also be used to
6 secure the stent in position, the tissue at around
7 the flange preventing movement of the stent from a
8 first compartment to a second compartment.

9
10 In a preferred embodiment, the valve comprises at
11 least one cantilever member, having a first end and
12 a second end, said cantilever member being pivoted
13 at said first end to the stent, the cantilever
14 member being resiliently pivotable from a first
15 extended position in which the valve is in a closed
16 position to a second position in which the valve is
17 open. In a preferred example of such an embodiment
18 when the second end of the cantilever member is in
19 the extended position the material forming the valve
20 and defining the aperture of the valve, when in the
21 open position, is pulled such that the area of the
22 aperture formed by the material is decreased.

23
24 In such a preferred example of this embodiment,
25 movement of fluid in a first direction through the
26 stent causes the second end of the cantilever member
27 to resiliently move radially inwards towards the
28 central longitudinal axis of the stent. This
29 movement of the second end of the cantilever member
30 causes the material forming the valve and defining
31 the aperture of the valve to form a larger aperture
32 (preferably substantially circular) in cross section

1 enabling increased fluid to flow through the valve.
2 As the fluid flow in the first direction is reduced
3 or when there is no fluid flow in the first
4 direction, the cantilever member resiliently pivots
5 to the extended position. This movement of the
6 second end of the cantilever member to the extended
7 position causes the material forming the valve and
8 defining the aperture of the valve to be pulled to
9 form an aperture of reduced area in cross section.
10 As the aperture has less area in cross section than
11 the substantially circular aperture, fluid flow in
12 both the first and second directions is restricted.
13
14 More preferably, the valve comprises two cantilever
15 members. In this embodiment the two cantilever
16 members are resiliently pivoted at first ends of the
17 members to the stent. When no fluid is flowing
18 through the stent the second ends of the cantilever
19 members pivot radially outwards to an extended
20 position. Preferably radially greater than the
21 circumference of the stent. When the second ends of
22 the cantilever members are in the extended positions
23 the material forming the valve and defining the
24 aperture of the valve when in the open position is
25 held such that the area of the aperture formed by
26 the material is decreased and forms an ellipsoid in
27 cross section.
28
29 Such an embodiment may function as follows: Movement
30 of fluid in a first direction through the stent
31 causes the second ends of the cantilever members to
32 resiliently move radially inwards towards the

1 central longitudinal axis of the stent. This
2 movement of the second ends of the cantilever
3 members causes the material forming the valve and
4 defining the aperture of the valve to form a
5 substantially circular aperture in cross section
6 enabling blood to flow through the valve.
7

8 As the fluid flow in the first direction is reduced,
9 or when there is no fluid flow in the first
10 direction, the second ends of the cantilever members
11 again resiliently pivot to an extended position.
12 The movement of the second ends of the cantilever
13 members to their extended positions again causes the
14 material forming the valve and defining the aperture
15 of the valve to be pulled to form an ellipsoid
16 aperture of reduced area in cross section. As the
17 aperture has less area in cross section than the
18 substantially circular aperture, fluid flow in both
19 the first and second directions is restricted.
20

21 With the circular cross section increased flow
22 through the stent is enabled and with the
23 ellipsoidal cross section flow in the second
24 direction is minimised.
25

26 In such an embodiment, the aperture formed by the
27 resilient material is preferably pulled from a
28 substantially circular cross section to a
29 substantially ellipsoidal cross section, which, in
30 use, restricts the flow of fluid from a second
31 compartment toward a first compartment.
32

1 Preferably the stent is constructed such that it can
2 be expanded in diameter from a "collapsed"
3 configuration to an "expanded" configuration,
4 wherein, in the collapsed configuration, the stent
5 is of narrower diameter than in the expanded
6 configuration.

7
8 Such a structure enables the stent to be suitably
9 placed in the body in the narrowed collapsed
10 configuration and then expanded from its collapsed
11 configuration to a fully expanded configuration.

12
13 The diameter of the stent can be increased from the
14 collapsed to expanded position using any suitable
15 procedures, for example, using a balloon angioplasty
16 procedure.

17
18 In order to position such a stent, the stent, in a
19 collapsed position, may be delivered to the desired
20 location in the body, for example, the heart muscle
21 between the left ventricle and a coronary artery on
22 a catheter. The suitably located stents may then be
23 deployed by expanding a balloon placed in the stent
24 such that the diameter of the stent increases from
25 that of the collapsed stent position to the
26 increased diameter of the stent in the expanded
27 position.

28
29 Further to expanding the diameter of the stent by
30 the balloon the stent locks in the expanded
31 position, holding the stent against the heart muscle

1 and maintaining the stent in its expanded position
2 with increased diameter.

3
4 The collapsed stent can be placed by suitable
5 minimally invasive techniques such as percutaneous
6 delivery.

7
8 In an alternative embodiment the stent may be
9 constructed of material with memory such that once
10 suitably placed in the body the diameter of the
11 stent expands from a collapsed position to a fully
12 expanded position.

13
14 For example, in such an embodiment, the stent may
15 adopt a collapsed position at low temperatures, for
16 example temperatures below body temperature, but an
17 expanded position at body temperature.

18
19 In one preferred embodiment, the valve of the stent
20 is moved to a closed position on increasing the
21 diameter of the stent from a collapsed position to
22 an expanded position when the stent is suitably
23 positioned in the body.

24
25 In particularly preferred embodiments the valve
26 comprises at least one cantilever member as
27 discussed above. Expansion of diameter of the stent
28 e.g. on deployment of the stent, causes the valve to
29 adopt the closed configuration.

30
31 In this embodiment, the cantilever member may be
32 resiliently pivoted at a first end to the stent such

1 that on expansion of the diameter of the stent a
2 second end of the cantilever member pivots to an
3 extended position in which the material forming the
4 valve and defining the aperture of the valve when in
5 the open position is pulled such that the area of
6 the aperture formed by the material is decreased.

7
8 More preferably the valve comprises two cantilever
9 members which, on deployment of the stent, cause the
10 diameter of the stent to expand from a collapsed
11 configuration in which the valve portion of the
12 stent is in an open position to an expanded
13 configuration in which the valve is in a closed
14 position. With the circular cross section increased
15 flow through the stent is enabled and with the
16 ellipsoidal cross section flow in the second
17 direction is minimised.

18
19 In such an embodiment, the aperture formed by the
20 resilient material is preferably pulled from a
21 substantially circular cross section to a
22 substantially ellipsoidal cross section, which, in
23 use, restricts the flow of fluid from a second
24 compartment toward a first compartment.

25
26 The diameter and length of the stent depends on its
27 use. For example, the stent may be of suitable
28 length to extend between the left ventricle of heart
29 and coronary artery.

30
31 Preferably the stent is two to fifteen millimetres
32 in diameter.

1

2 The stent may be constructed such that a number of
3 stents may be positioned "end to end" to increase
4 the effective length of the stent arrangement.

5

6 Thus, in one preferred embodiment the stent is
7 resiliently deformable at at least one end to
8 receive and enable connection with a second stent.

9

10 In an alternative embodiment the stent may be shaped
11 at one or both ends to enable connection to a second
12 stent.

13

14 The stent may comprise drug coatings or chemical and
15 / or mechanical coatings such as a TEFLON TM membrane
16 to minimise stenosis.

17

18 As described above, stents of the present invention
19 may be used to link or repair two cardiovascular
20 compartments.

21

22 For example, stents of the invention may be used to
23 link a coronary artery to the left ventricle of the
24 heart.

25

26 Stents of the present invention may also be used in
27 non coronary structures e.g. non coronary veins and
28 / or arteries.

29

30 For example, the stents may be used to link a first
31 portion of an ascending venous structure such as the
32 saphenous vein and a second portion of the same

1 ascending venous structure. If the region between
2 the first and second portions of the femoral artery
3 is damaged or occluded, a stent of the invention may
4 be located between the first and second portions to
5 enable the movement of blood from the first portion
6 to the second portion.

7
8 Thus in use, a stent of the present invention may be
9 provided between a first and second portion of a
10 vein e.g. a saphenous vein, to allow blood to flow
11 from the first portion to the second portion, but
12 restrict blood flow from the second portion to the
13 first portion. Such an arrangement could be used to
14 treat varicose veins.

15
16 In a second aspect of the present invention there is
17 provided a method for treating a full or partial
18 occlusion of a blood vessel comprising the step of
19

20 providing stent means wherein said stent means
21 comprise at least one stent of the first aspect
22 of the invention,

23
24 a first end of the lumen of the stent means
25 being in communication with a cardiovascular
26 compartment on one side of the occlusion,

27
28 the second end of the lumen of the stent means
29 being in communication with a cardiovascular
30 compartment on the other side of the occlusion
31 allowing blood flow from the first side to the

1 second side of the cardiovascular compartment
2 through the lumen of the stent means.

3

4 The cardiovascular compartments on each side of the
5 occlusion may be in same the blood vessel in which
6 the occlusion is present.

7

8 In alternative embodiments the cardiovascular
9 compartments may be different compartments, for
10 example the left ventricle of the heart and a
11 coronary artery.

12

13 The stent means may comprise a single stent.
14 Alternatively the stent means may comprise a
15 plurality of stents longitudinally aligned to allow
16 the flow of blood from a stent at a first end of the
17 stent means to a stent at a second end of the stent
18 means.

19

20 Preferably the stent means comprise a single stent
21 of the first aspect of the invention.

22

23 In preferred embodiments the method further
24 comprises the step of positioning the stent means
25 between the compartments, increasing the diameter of
26 the stent means from a reduced diameter in a
27 collapsed position to an increased diameter in an
28 expanded position.

29

30 In particularly preferred embodiments the method
31 comprises the steps of

32

1 inserting the stent into position between a
2 first cardiovascular compartment and a second
3 cardiovascular compartment;
4
5 expanding the diameter of the stent such that
6 the valve is moved to the closed position, but
7 can move to the open position when fluid flows
8 in a first direction from a first
9 cardiovascular compartment to a second
10 cardiovascular compartment.

11
12 According to a further aspect of the invention there
13 is provided a method for treating varicose veins
14 comprising positioning stent means comprising at
15 least one stent of the first aspect of the invention
16 in a vein or replacing all or part of a vein with
17 stent means comprising at least one stent of the
18 first aspect of the invention.

19
20 As above, stent means may comprise a plurality of
21 stents longitudinally aligned to allow the flow of
22 fluid from a stent at a first end of the stent means
23 to a stent at a second end of the stent means.

24
25 As described above, in a preferred embodiment of a
26 first aspect of the invention a stent comprising a
27 valve comprising at least one cantilever member is
28 provided. The use of such a valve is not limited to
29 uses within the body. Accordingly, in a further
30 independent aspect there is provided tube means,
31 said tube means comprising a valve which comprises
32 at least one cantilever member, having a first end

1 and a second end, said cantilever member being
2 pivoted at said first end to the tube, the
3 cantilever member being resiliently pivotable from a
4 first extended position in which the valve is in a
5 closed position to a second position in which the
6 valve is open.

7
8 Tubes comprising such valves may be used to link a
9 first cardiovascular compartment with a compartment
10 in a cardiovascular device or vice versa.

11
12 In a further embodiment tubes comprising such valves
13 may be used to link first and second compartments in
14 a device to transport fluid, for example blood.

15
16 For example, such tubes comprising at least one
17 cantilever member can be used in machines or devices
18 used to move fluid, for example blood, such as
19 dialysis machines.

20
21 A further independent aspect of the present
22 invention is a device for the movement of fluid.

23
24 Preferably the fluid is blood.

25
26 The present invention will now be described, by way
27 of example only, with reference to the accompanying
28 figures in which;

29
30 Figure 1 is an illustration of an embodiment of
31 a stent of the present invention extending from

1 the left ventricle of the heart into the
2 coronary artery;

3
4 Figure 2 is an enlarged view of an embodiment
5 of a stent of the present invention connecting
6 the left ventricle of the heart to the coronary
7 artery;

8
9 Figure 3 is an illustration of an embodiment of
10 a stent of the present invention wherein a
11 second end of the stent is in a closed
12 position;

13
14 Figure 4 (A) is an illustration of an
15 embodiment of a stent in a collapsed form, (B)
16 is an illustration of an embodiment of a stent
17 of the present invention in an expanded form;

18
19 Figure 5 is an illustration of an embodiment of
20 a stent of the present invention where a second
21 end of a stent is in an open position;

22
23 Figure 6 is an illustration of at least two
24 embodiments of stents of the present invention
25 aligned along their longitudinal axes such that
26 blood can flow from the lumen of a first stent
27 to the lumen of a second adjacent stent; and

28
29 Figure 7 is an illustration of stents according
30 to an embodiment of the present invention
31 aligned along their longitudinal length wherein
32 the first stent has a shaped end to receive the

1 second stent and another stent is deformable to
2 receive a stent inside one end.

3

4 As shown in figure 1, the coronary artery 10 is
5 known to branch off the aorta 12 and be positioned
6 along the external surface of the heart wall 14.

7

8 Following oxygenation of the blood, the oxygenated
9 blood flows from the heart 16 into the aorta 12 and
10 onto the rest of the body. Some of the oxygenated
11 blood is circulated along the coronary artery 10 in
12 order to oxygenate the muscles of the heart. In
13 some individuals an occlusion is formed within the
14 coronary artery due to plaque build up. These
15 occlusions can lead to a variety of symptoms and
16 diseases ranging from mild angina to heart attack.

17

18 In order to allow blood flow around the occlusion
19 within the coronary artery and to at least partially
20 restore the flow of oxygenated blood through the
21 coronary artery, it is possible to bypass the
22 blocked portion of the coronary artery by providing
23 a stent 18 which extends from the left ventricle 20
24 of the heart into the coronary artery 10, as shown
25 in figure 2. Location of the stent 18 as shown in
26 figure 2 allows blood to flow unobstructed from the
27 left ventricle 20 of the heart to the coronary
28 artery 10.

29

30 Allowing blood flow past or around occlusions of the
31 coronary artery 10 using a stent 18 is preferable to
32 traditional bypass surgery in that the stent 18 may

1 be located and fitted using minimally invasive
2 techniques. Generally the stents previously used to
3 connect the left ventricle 20 of the heart to the
4 coronary artery 10 are stents formed by hollow tubes
5 comprising biocompatible material such as titanium
6 alloys, nickel alloys or biocompatible polymers.
7 These tubes may be provided and located between the
8 left ventricle 20 of the heart and the coronary
9 artery 10 in a collapsed position and when suitably
10 located, expanded from a collapsed position to a
11 fully expanded position, using an inflatable balloon
12 catheter or other method.

13

14 Although such stents allow the flow of blood from
15 the left ventricle 20 of the heart into the coronary
16 artery, no artificial or mechanical means are
17 present on conventional stents to restrict the
18 backflow of blood.

19

20 As shown in figure 3, a stent of the present
21 invention is provided with a synthetic valve 22, one
22 example of the valve being a portion of flexible
23 resilient material located at the second end 24 of
24 the stent. This flexible resilient material is
25 preferably integral with the rest of the stent.

26

27 The valve may be formed during manufacture of the
28 stent, prior to insertion of the stent into the
29 body.

30

31 Alternatively, as shown in the embodiment of the
32 stent in figure 4, the valve can be created by the

1 pivotal movement of cantilever members during the
2 movement of the stent from a collapsed position to
3 an expanded position, while the stent is located in
4 the body.

5
6 As shown in figure 4a, in this embodiment, in a
7 collapsed position, the resilient material, held by
8 two cantilever members 21, forms a substantially
9 cylindrical aperture 28.

10
11 The cantilever members are conjoined to the stent at
12 a first end only and from the rigid biocompatible
13 metal portion 23 of the stent. On deployment
14 (expansion of diameter) of the stent, the second
15 ends of the cantilevers move away from each other to
16 an extended position. This movement pulls the
17 resilient material such that its cross sectional
18 shape is changed from substantially circular to
19 substantially ellipsoidal. The change in the cross
20 sectional shape restricts the flow of blood in a
21 second direction from the second compartment into
22 the first compartment through the stent. Blood flow
23 through the stent from a first compartment to a
24 second compartment causes the material of the
25 leaflets to be pushed such that the cantilever
26 members resiliently move towards each other and the
27 aperture of the valve becomes substantially circular
28 in cross section. The area of the circular cross
29 section is larger than the ellipsoidal cross section
30 and blood can thus easily flow from the first
31 compartment to the second compartment. During
32 diastole, when blood is not being pushed from the

1 first compartment to the second compartment, the
2 pressure of the blood on the material of the valve
3 decreases. The second ends of the resilient
4 cantilever members can again move away from each
5 other and cause the valve material to form an
6 ellipsoidal cross section.

7
8 It can be appreciated that if more than two
9 cantilevers are used for example, three, four or
10 five cantilevers, then on deployment, the cross
11 sectional shape will not be elliptical, but
12 substantially triangular, rectangular or pentacle
13 shaped. Different shaped openings may be used as
14 appropriate to restrict the flow of blood from the
15 second compartment to the first compartment. In
16 addition, different shaped openings can be chosen to
17 minimise pressure on the arterial wall caused by the
18 cantilever members.

19
20 In one embodiment, a valve formed from resilient
21 material does not require expansion of the diameter
22 of the stent to cause the resilient material to
23 adopt the closed position. In this embodiment
24 cantilever members are not required to pull the
25 material of the valve to a closed position and the
26 valve is manufactured in the closed position. Blood
27 flow in a first direction from the first compartment
28 towards the second compartment causes the resilient
29 material to adopt an open position.

30
31 In addition to the cantilever members disclosed
32 herein, different methods of urging the resilient

1 material to a closed position following expansion of
2 a stent structure from a collapsed position can be
3 envisaged.

4
5 During systole (contraction of the heart) the blood
6 is pumped by the heart through the stent 18 from the
7 first end 26 located at the left ventricle 20 of the
8 heart towards the second end 24 of the stent located
9 at the coronary artery. On contraction of the
10 heart, the blood of the left ventricle of the heart
11 is moved in a first direction through the stent
12 causing the valve to move from an ellipsoidal shape
13 (closed position) to an open (circular cross
14 sectional shape) position.

15
16 In the closed position the ellipsoidal shape causes
17 the area through which blood can flow from the
18 second compartment to the first compartment to be
19 reduced to 10% the area of the open position of the
20 valve. The backflow of blood is thus reduced when
21 blood is not being pumped through the stent from the
22 first compartment to the second compartment.

23
24 Typically reflux of blood through the valve from the
25 second compartment to the first compartment may be
26 25% that which would be expected if the valve is in
27 the open position.

28
29 The movement of the resilient material in this
30 manner, from an ellipsoidal shape (closed position)
31 towards a circular shape (open position), increases
32 the area of the aperture 28 through which the blood

1 can flow from the first compartment (in this case
2 the left ventricle of the heart) into the second
3 compartment (in this case the coronary artery) and
4 allows the unobstructed flow of blood through the
5 valve.

6
7 As the pressure of the blood flow through the valve
8 in a first direction decreases, the resilient
9 material is urged by the material (and in particular
10 embodiments the cantilever members of the rigid
11 portion of the stent) to cause the valve to adopt a
12 resting position, wherein the aperture of the valve
13 into the coronary artery forms an ellipsoidal shape.
14 This change in shape of the aperture reduces the
15 area of the aperture located at the second
16 compartment and minimises the blood flow from the
17 coronary artery into the left ventricle of the
18 heart.

19
20 Movement of the stent from a collapsed position to
21 an expanded position causes the stent to be gripped
22 by the heart muscle. A flange or other projection
23 may also be provided on the stent to aid location of
24 the stent.

25
26 As shown in figures 6 and 7 at least two stents can
27 be aligned along their longitudinal axes such that
28 blood can be communicated from the lumen of a first
29 stent to the lumen of a second adjacent stent. By
30 aligning several stents together, blood may be moved
31 from a first proximal position to a second distal
32 position, either between two different

1 cardiovascular compartments such as the left
2 ventricle of the heart and a coronary artery or
3 within the same cardiovascular compartments such as
4 a blood vessel.

5
6 By aligning a number of stents along their
7 longitudinal axis it is possible to allow blood flow
8 to be effected over a relatively large distance. In
9 addition, as each of the stents comprise a valve,
10 the stents more closely mimic the situation in
11 actual veins preventing the backflow of blood and
12 allowing blood to be moved upwards. An example of
13 when the blood may be required to be moved upwards
14 is in the leg of a patient when said patient is
15 standing.

16
17 The valves present on each of the stents allow blood
18 to be pushed through the valve on contraction of the
19 heart, but minimise the backward movement of the
20 blood during diastole. This allows blood to be
21 moved up the leg and through the body.

22
23 To allow the stents to be conjoined to each other, a
24 first end of a stent may be capable of deformation
25 (as shown in figure 7 (30)) to allow a second stent
26 to be partially inserted therein. Alternatively or
27 additionally the stent may also be widened (figure 7
28 (32)) to allow ingress of a second stent as shown in
29 figure 7.

30
31 It can be appreciated that various improvements and
32 modifications can be made without departing from the

1 scope of the present invention. In particular it
2 can be envisaged that the valve may be formed from
3 at least two leaflets, which in a resting position
4 are urged towards each other minimising blood flow
5 from the second cardiovascular compartment into the
6 first cardiovascular compartment. On movement of
7 blood in a first direction through the stent, from
8 the first compartment to the second compartment,
9 these leaflets may be pushed apart from each other,
10 enabling blood flow from the first compartment into
11 the second compartment. During diastole the two
12 leaflets of the valve will be urged towards each
13 other due to the resilience of the material.
14 Alternatively, different methods may be used to
15 align the stents along their longitudinal length
16 such as providing junction means.

17

18

19